

§ 170.580 ONC review of certified health IT.

(a) *Direct review*—(1) *Purpose*. ONC may directly review certified health IT or a health IT developer's actions or practices to determine whether either conform to the requirements of the ONC Health IT Certification Program.

(2) *Circumstances that may trigger review*—(i) *Certified health IT causing or contributing to unsafe conditions*. ONC may initiate direct review under this section if it has a reasonable belief that certified health IT may not conform to the requirements of the Program because the certified health IT may be causing or contributing to conditions that present a serious risk to public health or safety, taking into consideration—

(A) The potential nature, severity, and extent of the suspected conditions;

(B) The need for an immediate or coordinated governmental response; and

(C) If applicable, information that calls into question the validity of the health IT's certification or maintenance thereof under the Program.

(ii) *Impediments to ONC-ACB oversight of certified health IT*. ONC may initiate direct review under this section if it has a reasonable belief that certified health IT may not conform to requirements of the Program and the suspected non-conformity presents issues that—

(A) May require access to confidential or other information that is not available to an ONC-ACB;

(B) May require concurrent or overlapping review by two or more ONC-ACBs; or

(C) May exceed an ONC-ACB's resources or expertise.

(iii) *Noncompliance with a Condition and Maintenance of Certification requirement*. ONC may initiate direct review under this section if it has a reasonable belief that a health IT developer has not complied with a Condition or Maintenance of Certification requirement under subpart D of this part.

(3) *Relationship to ONC-ACBs and ONC-ATLs*. (i) ONC's review of certified health IT or a health IT developer's actions or practices is independent of, and may be in addition to, any surveillance of certified health IT conducted by an ONC-ACB.

(ii) ONC may assert exclusive review of certified health IT as to any matters under review by ONC and any similar matters under surveillance by an ONC-ACB.

(iii) ONC's determination on matters under its review is controlling and supersedes any determination by an ONC-ACB on the same matters.

(iv) An ONC-ACB and ONC-ATL shall provide ONC with any available information that ONC deems relevant to its review of certified health IT or a health IT developer's actions or practices.

(v) ONC may end all or any part of its review of certified health IT or a health IT developer's actions or practices under this section at any time and refer the applicable part of the review to the relevant ONC-ACB(s) if ONC determines that doing so would serve the effective administration or oversight of the ONC Health IT Certification Program.

(4) *Coordination with the Office of Inspector General.* (i) ONC may coordinate its review of a claim of information blocking with the Office of Inspector General or defer to the Office of Inspector General to lead a review of a claim of information blocking.

(ii) ONC may rely on Office of Inspector General findings to form the basis of a direct review action.

(b) *Notice—(1) Notice of potential non-conformity—(i) Circumstances that may trigger notice of potential non-conformity.* At any time during its review of certified health IT or a health IT developer's actions or practices under paragraph (a) of this section, ONC may send a notice of potential non-conformity if it has a reasonable belief that certified health IT or a health IT developer's actions or practices may not conform to the requirements of the ONC Health IT Certification Program.

(ii) *Health IT developer response.* (A) The health IT developer must respond to the notice of potential non-conformity by:

(1) Cooperating with ONC and/or a third party acting on behalf of ONC;

(2) Providing ONC and/or a third party acting on behalf of ONC access, including in accordance with paragraph (b)(3) of this section, to the certified health IT under review;

(3) Providing ONC with a written explanation and all supporting documentation addressing the potential non-conformity within 30 days, or within the adjusted timeframe set in accordance with paragraph (b)(1)(ii)(B) of this section.

(B) ONC may adjust the 30-day timeframe specified in paragraph (b)(1)(ii)(A)(3) of this section to be shorter or longer based on factors including, but not limited to:

(1) The type of certified health IT and certification in question;

(2) The type of potential non-conformity to be corrected;

(3) The time required to correct the potential non-conformity; and

(4) Issues of public health or safety.

(iii) *ONC determination.* After receiving the health IT developer's written explanation and supporting documentation as required by paragraph (b)(1)(ii)(A)(3) of this section, ONC shall do one of the following:

(A) Issue a written determination ending its review.

(B) Request additional information and continue its review in accordance with a new timeframe ONC establishes under (b)(1)(ii)(A)(3) and (b)(1)(ii)(B) of this section.

(C) Substantiate a non-conformity and issue a notice of non-conformity.

(D) Issue a notice of proposed termination if the health IT is under review in accordance with paragraph (a)(2)(i) or (ii) of this section.

(2) *Notice of non-conformity*—(i) *Circumstances that may trigger notice of non-conformity.* At any time during its review of certified health IT or a health IT developer's actions or practices under paragraph (a) of this section, ONC may send a notice of non-conformity to the health IT developer if it determines that certified health IT or a health IT developer's actions or practices does not conform to the requirements of the ONC Health IT Certification Program.

(ii) *Health IT developer response.* (A) The health IT developer must respond to the notice of non-conformity by:

(1) Cooperating with ONC and/or a third party acting on behalf of ONC;

(2) Providing ONC and/or a third party acting on behalf of ONC access, including in accordance with paragraph (b)(3) of this section, to the certified health IT under review;

(3) Providing ONC with a written explanation and all supporting documentation addressing the non-conformity within 30 days, or within the adjusted timeframe set in accordance with paragraph (b)(1)(ii)(B) of this section; and

(4) Providing a proposed corrective action plan consistent with paragraph (c) of this section.

(B) ONC may adjust the 30-day timeframe specified in paragraph (b)(2)(ii)(A)(3) of this section to be shorter or longer based on factors including, but not limited to:

(1) The type of certified health IT and certification in question;

(2) The type of non-conformity to be corrected;

(3) The time required to correct the non-conformity; and

(4) Issues of public health or safety.

(iii) *ONC determination.* After receiving the health IT developer's response provided in accordance with paragraph (b)(2)(ii) of this section, ONC shall either issue a written determination ending its review or continue with its review under the provisions of this section.

(3) *Records access.* In response to a notice of potential non-conformity or notice of non-conformity, a health IT developer shall make available to ONC and for sharing within HHS, with other federal departments, agencies, and offices, and with appropriate entities including, but not limited to, third-parties acting on behalf of ONC:

(i) All records related to the development, testing, certification, implementation, maintenance and use of its certified health IT;

(ii) Any complaint records related to the certified health IT;

(iii) All records related to the Condition(s) and Maintenance of Certification requirements, including marketing and distribution records, communications, and contracts; and

(iv) Any other relevant information.

(c) *Corrective action plan and procedures*—(1) *Applicability*. If ONC determines that certified health IT or a health IT developer's action or practice does not conform to requirements of the ONC Health IT Certification Program, ONC shall notify the health IT developer of its determination and require the health IT developer to submit a proposed corrective action plan.

(2) ONC shall provide direction to the health IT developer as to the required elements of the corrective action plan, which shall include such required elements as ONC determines necessary to comprehensively and expeditiously resolve the identified non-conformity(ies). The corrective action plan shall, in all cases, at a minimum include the following required elements:

(i) An assessment and description of the nature, severity, and extent of the non-conformity;

(ii) Identification of all potentially affected customers;

(iii) A detailed description of how the health IT developer will promptly ensure that all potentially affected customers are notified of the non-conformity and plan for resolution;

(iv) A detailed description of how and when the health IT developer will resolve the identified non-conformity and all issues, both at the locations where the non-conformity was identified and for all affected customers;

(v) A detailed description of how the health IT developer will ensure that the identified non-conformity and all issues are resolved;

(vi) A detailed description of the supporting documentation that will be provided to demonstrate that the identified non-conformity and all issues are resolved; and

(vii) The timeframe under which all elements of the corrective action plan will be completed.

(viii) An explanation of, and agreement to execute, the steps that will be prevent the non-conformity from re-occurring.

(3) When ONC receives a proposed corrective action plan (or a revised proposed corrective action plan), it shall either approve the proposed corrective action plan or, if the plan does not adequately address all required elements, instruct the health IT developer to submit a revised proposed corrective action plan within a specified period of time.

(4) The health IT developer is responsible for ensuring that a proposed corrective action plan submitted in accordance with paragraph (b)(2)(ii)(A)(4) of this section or a revised corrective action plan submitted in accordance with paragraph (c)(3) of this section adequately addresses all required elements as determined by ONC no later than 90 days after the health IT developer's receipt of a notice of non-conformity.

(5) Health IT developers may request extensions for the submittal and/or completion of corrective action plans. In order to make these requests, health IT developers must submit a written statement to ONC that explains and justifies the extension request. ONC will evaluate each request individually and will make decisions on a case-by-case basis.

(6) Upon fulfilling all of its obligations under the corrective action plan, the health IT developer must submit an attestation to ONC, which serve as a binding official statement by the health IT developer that it has fulfilled all of its obligations under the corrective action plan.

(7) ONC may reinstitute a corrective action plan if it later determines that a health IT developer has not fulfilled all of its obligations under the corrective action plan as attested in accordance with paragraph (c)(6) of this section.

(d) *Suspension.* (1) ONC may suspend the certification of a Health IT Module at any time if ONC has a reasonable belief that the certified health IT may present a serious risk to public health or safety.

(2) When ONC decides to suspend a certification, ONC will notify the health IT developer of its determination through a notice of suspension.

(i) The notice of suspension will include, but may not be limited to:

(A) An explanation for the suspension;

(B) Information supporting the determination;

(C) The consequences of suspension for the health IT developer and the Health IT Module under the ONC Health IT Certification Program; and

(D) Instructions for appealing the suspension.

(ii) A suspension of a certification will become effective upon the date specified in the notice of suspension.

(3) The health IT developer must notify all potentially affected customers of the identified non-conformity(ies) and suspension of certification in a timely manner.

(4) When a certification is suspended, the health IT developer must cease and desist from any marketing, licensing, and sale of the suspended Health IT Module as “certified” under the ONC Health IT Certification Program from that point forward until such time ONC cancels the suspension in accordance with paragraph (d)(6) of this section.

(5) The certification of any health IT produced by a health IT developer that has the certification of one of its Health IT Modules suspended under the Program is prohibited, unless ONC cancels a suspension in accordance with paragraph (d)(6) of this section.

(6) ONC may cancel a suspension at any time if ONC no longer has a reasonable belief that the certified health IT presents a serious risk to public health or safety.

(e) *Proposed termination*—(1) *Applicability*. Excluding situations of noncompliance with a Condition or Maintenance of Certification requirement under subpart D of this part, ONC may propose to terminate a certification issued to a Health IT Module if:

(i) The health IT developer fails to timely respond to any communication from ONC, including, but not limited to:

(A) Fact-finding;

(B) A notice of potential non-conformity within the timeframe established in accordance with paragraph (b)(1)(ii)(A)(3) of this section;

(C) A notice of non-conformity within the timeframe established in accordance with paragraph (b)(2)(ii)(A)(3) of this section; or

(D) A notice of suspension.

(ii) The information or access provided by the health IT developer in response to any ONC communication, including, but not limited to: Fact-finding, a notice of potential non-conformity, or a notice of non-conformity is insufficient or incomplete;

(iii) The health IT developer fails to cooperate with ONC and/or a third party acting on behalf of ONC;

(iv) The health IT developer fails to timely submit in writing a proposed corrective action plan;

(v) The health IT developer fails to timely submit a corrective action plan that adequately addresses the elements required by ONC as described in paragraph (c) of this section;

(vi) The health IT developer does not fulfill its obligations under the corrective action plan developed in accordance with paragraph (c) of this section; or

(vii) ONC concludes that a certified health IT's non-conformity(ies) cannot be cured.

(2) When ONC decides to propose to terminate a certification, ONC will notify the health IT developer of the proposed termination through a notice of proposed termination.

(i) The notice of proposed termination will include, but may not be limited to:

(A) An explanation for the proposed termination;

(B) Information supporting the proposed termination; and

(C) Instructions for responding to the proposed termination.

(3) The health IT developer may respond to a notice of proposed termination, but must do so within 10 days of receiving the notice of proposed termination and must include appropriate documentation explaining in writing why its certification should not be terminated.

(4) Upon receipt of the health IT developer's written response to a notice of proposed termination, ONC has up to 30 days to review the information submitted by the health IT developer and make a determination. ONC may extend this timeframe if the complexity of the case requires additional time for ONC review. ONC will, as applicable:

(i) Notify the health IT developer in writing that it has ceased all or part of its review of the health IT developer's certified health IT.

(ii) Notify the health IT developer in writing of its intent to continue all or part of its review of the certified health IT under the provisions of this section.

(iii) Proceed to terminate the certification of the health IT under review consistent with paragraph (f) of this section.

(f) *Termination*—(1) *Applicability*. The National Coordinator may terminate a certification if:

(i) A determination is made that termination is appropriate after considering the information provided by the health IT developer in response to the proposed termination notice;

(ii) The health IT developer does not respond in writing to a proposed termination notice within the timeframe specified in paragraph (e)(3) of this section; or

(iii) A determination is made that the health IT developer is noncompliant with a Condition or Maintenance of Certification requirement under subpart D of this part or for the following circumstances when ONC exercises direct review under paragraph (a)(2)(iii) of this section:

(A) The health IT developer fails to timely respond to any communication from ONC, including, but not limited to:

(1) Fact-finding;

(2) A notice of potential non-conformity within the timeframe established in accordance with paragraph (b)(1)(ii)(A)(3) of this section; or

(3) A notice of non-conformity within the timeframe established in accordance with paragraph (b)(2)(ii)(A)(3) of this section.

(B) The information or access provided by the health IT developer in response to any ONC communication, including, but not limited to: Fact-finding, a notice of potential non-conformity, or a notice of non-conformity is insufficient or incomplete;

(C) The health IT developer fails to cooperate with ONC and/or a third party acting on behalf of ONC;

(D) The health IT developer fails to timely submit in writing a proposed corrective action plan;

(E) The health IT developer fails to timely submit a corrective action plan that adequately addresses the elements required by ONC as described in paragraph (c) of this section;

(F) The health IT developer does not fulfill its obligations under the corrective action plan developed in accordance with paragraph (c) of this section; or

(G) ONC concludes that the non-conformity(ies) cannot be cured.

(2) When ONC decides to terminate a certification, ONC will notify the health IT developer of its determination through a notice of termination.

(i) The notice of termination will include, but may not be limited to:

(A) An explanation for the termination;

(B) Information supporting the determination;

(C) The consequences of termination for the health IT developer and the Health IT Module under the ONC Health IT Certification Program; and

(D) Instructions for appealing the termination.

(ii) A termination of a certification will become effective after the following applicable occurrence:

(A) The expiration of the 10-day period for filing a statement of intent to appeal in paragraph (g)(3)(i) of this section if the health IT developer does not file a statement of intent to appeal.

(B) The expiration of the 30-day period for filing an appeal in paragraph (g)(3)(ii) of this section if the health IT developer files a statement of intent to appeal, but does not file a timely appeal.

(C) A final determination to terminate the certification per paragraph (g)(7) of this section if a health IT developer files an appeal.

(3) The health IT developer must notify all potentially affected customers of the identified non-conformity(ies) and termination of certification in a timely manner.

(4) ONC may rescind a termination determination before the termination becomes effective if ONC determines that termination is no longer appropriate.

(g) *Appeal*—(1) *Basis for appeal*. A health IT developer may appeal an ONC determination to suspend or terminate a certification issued to a Health IT Module and/or an ONC determination to issue a certification ban under § 170.581(a)(2) if the health IT developer asserts:



(i) ONC incorrectly applied ONC Health IT Certification Program requirements for a:

(A) Suspension;

(B) Termination; or

(C) Certification ban under § 170.581(a)(2).

(ii) ONC's determination was not sufficiently supported by the information provided by ONC with its determination.

(2) *Method and place for filing an appeal.* A statement of intent to appeal followed by a request for appeal must be submitted to ONC in writing by an authorized representative of the health IT developer subject to the determination being appealed. The statement of intent to appeal and request for appeal must be filed in accordance with the requirements specified in the notice of:

(i) Termination;

(ii) Suspension; or

(iii) Certification ban under § 170.581(a)(2).

(3) *Time for filing a request for appeal.* (i) A statement of intent to appeal must be filed within 10 days of a health IT developer's receipt of the notice of:

(A) Suspension;

(B) Termination; or

(C) Certification ban under § 170.581(a)(2).

(ii) An appeal, including all supporting documentation, must be filed within 30 days of the filing of the intent to appeal.

(4) *Effect of appeal.* (i) A request for appeal stays the termination of a certification issued to a Health IT Module, but the Health IT Module is prohibited from being marketed, licensed, or sold as “certified” during the stay.

(ii) A request for appeal does not stay the suspension of a Health IT Module.

(iii) A request for appeal stays a certification ban issued under § 170.581(a)(2).

(5) *Appointment of a hearing officer.* The National Coordinator will assign the case to a hearing officer to adjudicate the appeal on his or her behalf.

(i) The hearing officer may not review an appeal in which he or she participated in the initial suspension, termination, or certification ban determination or has a conflict of interest in the pending matter.

(ii) The hearing officer must be trained in a nationally recognized ethics code that articulates nationally recognized standards of conduct for hearing officers/officials.

(6) *Adjudication.* (i) The hearing officer may make a determination based on:

(A) The written record, which includes the:

(1) ONC determination and supporting information;

(2) Information provided by the health IT developer with the appeal filed in accordance with paragraphs (g)(1) through (3) of this section; and

(3) Information ONC provides in accordance with paragraph (g)(6)(v) of this section; or

(B) All the information provided in accordance with paragraph (g)(6)(i)(A) and any additional information from a hearing conducted in-person, via telephone, or otherwise.

(ii) The hearing officer will have the discretion to conduct a hearing if he/she:

(A) Requires clarification by either party regarding the written record under paragraph (g)(6)(i)(A) of this section;

(B) Requires either party to answer questions regarding the written record under paragraph (g)(6)(i)(A) of this section; or

(C) Otherwise determines a hearing is necessary.

(iii) The hearing officer will neither receive witness testimony nor accept any new information beyond what was provided in accordance with paragraph (g)(6)(i) of this section.

(iv) The default process will be a determination in accordance with paragraph (g)(6)(i)(A) of this section.

(v) ONC will have an opportunity to provide the hearing officer with a written statement and supporting documentation on its behalf that clarifies, as necessary, its determination to suspend or terminate the certification or issue a certification ban.

(7) *Determination by the hearing officer.* (i) The hearing officer will issue a written determination to the health IT developer within 30 days of receipt of the appeal or within a timeframe agreed to by the health IT developer and ONC and approved by the hearing officer, unless ONC cancels the suspension or rescinds the termination determination.

(ii) The National Coordinator's determination on appeal, as issued by the hearing officer, is final and not subject to further review.

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